



[BILLING CODE 4140-01-P]

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

Proposed collection; 60-day comment request

Population Assessment of Tobacco and Health (PATH) Study –Wave 4 of Data Collection (NIDA)

**SUMMARY:** In compliance with the requirement of Section 3506(c) (2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing or request more information on the proposed project, contact: Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Boulevard, Room 5185; or call non-toll-free number (301) 443-8755; or E-mail your request, including your address to: PATHprojectofficer@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: Population Assessment of Tobacco and Health (PATH) Study –Wave 4 of Data Collection (NIDA) - 0925-0664, expiration date 8/31/2018 - REVISION– NIDA, NIH, in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a revision request (OMB number 0925-0664, expiration date 8/31/2018) for the Population Assessment of Tobacco and Health (PATH) Study to conduct the fourth wave of data collection. The PATH Study is a large national longitudinal cohort study on tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17. On an annual basis, the PATH Study conducts interviews with and collects biospecimens from adults and youth to help inform the development, implementation,

and evaluation of tobacco-product regulations by FDA in meeting its mission under the Family Smoking Prevention and Tobacco Control Act (TCA) to regulate tobacco products, including tobacco-product advertising, labeling, marketing, constituents, ingredients, and additives. The longitudinal design of the PATH Study provides it with the capacity to measure and report within-person changes and between-person differences in tobacco product use behaviors and health effects within the cohort over time. These data will help to inform regulatory decisions and actions by FDA and FDA's evaluations of associations between its regulations and tobacco use behaviors and health indicators in the population.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 105,079.

#### Estimated Annualized Burden Hours

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
1. Household Screener	Households	86,559	1	14/60	20,197
2. Shadow Youth Only Screener	Households	56,659	1	5/60	4,722
3. Extended Interview*	Adults – Adult respondents - previous wave	23,414	1	1	23,414
4. Consent for Extended Interview	Adults – New adults and Wave 1 youth respondents who age up to adult cohort - Wave 4	13,984	1	4/60	932
5. Individual Screener	Adults – New adults	9,152	1	6/60	915

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
6. Extended Interview*	Adults – New adults and Wave 1 youth respondents who age up to adult cohort - Wave 4	10,737	1	68/60	12,169
7. Consent for Biological Samples	Adults – New adults and Wave 1 youth respondents who age up to adult cohort - Wave 4	10,737	1	5/60	895
8. Biospecimen Collection: Urine	Adults	18,301	1	10/60	3,050
9. Biospecimen Collection: Blood	Adults – New adults and Wave 1 youth respondents who age up to adult cohort - Wave 4	4,832	1	18/60	1,450
10. Tobacco Use Form	Adults	23,133	1	5/60	1,928
11. Follow-up/Tracking Participant Information Form	Adults	34,151	2	8/60	9,107
12. Verification Interview	Adults	33,889	1	2/60	1,130
13. Validation Interview	Adults	301	1	4/60	20
14. Extended Interview**	Youth – Youth respondents - previous wave	8,627	1	35/60	5,032
15. Assent for Extended	Youth – New youth and	7,657	1	3/60	383

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Interview	shadow youth who age up to youth cohort - Wave 4				
16. Extended Interview**	Youth – New youth and shadow youth who age up to youth cohort - Wave 4	6,432	1	45/60	4,824
17. Assent for urine collection	Youth	15,059	1	5/60	1,255
18. Biospecimen Collection: Urine	Youth	10,239	1	10/60	1,707
19. Tobacco Use Form	Youth	10,239	1	5/60	853
20. Parent Interview	Adults – Parents of youth respondents - previous wave	8,800	1	16/60	2,347
21. Parent Permission and Consent for Parent Interview	Adults – Parents of new youth and parents of Shadow youth who age up to youth cohort - Wave 4	7,657	1	5/60	638
22. Parent Interview	Adults - Parents of new youth and parents of shadow youth who age up to youth cohort - Wave 4	6,561	1	19/60	2,078
23. Parent permission	Adults – Parents of youth	15,360	1	3/60	768

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
for urine collection	respondents - previous wave				
24. Follow-up/Tracking Participant Information Form for Youth (completed by parents)	Adults – Parents of youth respondents	15,059	2	8/60	4,016
25. Follow-up/Tracking Participant Information Form for sample shadow youth (completed by parents)	Adults – Parents of shadow youth	4,684	2	8/60	1,249
Total		49,210	496,116		105,079

Dated: April 5, 2016

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